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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,421	11/21/2001	Daniel A. Erlanson	SUNESIS.001A	4560

20995 7590 09/10/2003

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EXAMINER

EPPERSON, JON D.

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 09/10/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/990,421

Applicant(s)

ERLANSON ET AL.

Examiner

Jon D Epperson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-74 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Please note: The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1639**.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-43 and 50-68 drawn to a method for “screening” small organic ligand candidates against a Target Biological Molecule, classified variously in class 435, subclass 7.1, DIG 18, DIG 46.
 - II. Claims 44-47, 69, drawn to a product described as a “second ligand identified in claims 33 or claim 36” or a “molecule comprising a library member identified in step (v) of claim 50”, classified variously depending on the structure of the compound identified, for example, class 530, subclass 300+, 387.1+, 395.
 - III. Claims 48-49, 70-74 drawn to a product described as a “molecule comprising functional variants of said first and second ligands linked by a covalent bond” or “the molecule of claim 69 further comprising at least part of the small molecule extender used in step (ii) of claim 50, classified variously depending on the structure of the compound identified, for example, class 530, subclass 300+, 387.1+, 395.
2. The inventions are distinct, each from the other because of the following reasons:

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3. Groups I-III represent separate and patentably distinct inventions. Groups I is drawn to a patentably distinct method and Groups II-III are drawn to different products (i.e., e.g., which are directed to different purposes, use different materials, recite different method or process steps for the preparation of different product(s), screening of different characteristics, such as different binding affinities, different biochemical reaction conditions, etc. or lead to different final results). Therefore, the groups that describe these products and methods have different issues regarding patentability and enablement, and represent patentably distinct subject matter, which merits separate and burdensome searches. Art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing

4. Furthermore, if Applicant argues that Groups I and II or I and III are somehow related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different products or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, (1) the process as claimed can be used to make other and materially different products e.g., the products of Group I or the products of Group II. Furthermore, the process could also be used to find and “extended-extended” product. Furthermore, the inhibitors could be found without the use of the extended approach e.g., phage display screening.

5. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different methods and products would require

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completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

Species Election

6. This application contains claims directed to patentably distinct species of the claimed invention for Groups I-IV. Election is required as follows.

7. If applicant elects the invention of Group I, applicant is required to elect from the following patentably distinct species. Claim 1 is generic.

Subgroup 1: Species of target biological molecule (e.g., see claims 1, 7-8)

Applicant must elect, for the purposes of search, a *single species* of target biological molecule e.g., caspase-3 (see claim 8). Applicants should not elect a general class of proteins like “enzymes” because this election contains more than one patentably distinct species. Furthermore, Applicants must indicate the nucleophile (e.g., thiol, see claim 9) and its association (e.g., mutant Cys, see claim 11). Applicants must further indicate whether said nucleophile is “protected” or any other distinguishing characteristics (e.g., see claim 12).

Subgroup 2: Species of ligand candidate (e.g., see claims 1)

Applicant must elect for purposes of search a *single species* of ligand candidate. Furthermore, applicant must show *all* atoms and bonds that are necessary to define said ligand candidate. Applicant should NOT use general notations like R¹, R², etc. when defining the structure because these labels represent more than one chemical group and thus more than one compound would be erroneously elected.

Subgroup 3: Species of small molecule extender (e.g., see claims 1, 17-19 and figure 5)

Applicant must elect, for the purposes of search, a *single species* of small molecule extender e.g., 2,6-dichloro-benzoic acid 3-(2-acetylsulfanyl-acetylamino)-4-carboxy-2-o-xo-butyl ester.

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Subgroup 4: Species of conditions (e.g., see claims 1, 15-16)

Applicant must elect, for the purposes of search, a single species of conditions e.g., thiol exchange with dithiothreitol.

Subgroup 5: Species of irreversible covalent group (e.g., see claim 17)

Applicant must elect, for the purposes of search, a single species of irreversible covalent group e.g., thiol, protected thiol, or reversible disulfide group.

Subgroup 6: Species of reaction that SME can undergo (e.g., see claim 18)

Applicant must elect, for the purposes of search, a single species of reaction that SME can undergo e.g., Michael-type adduct with the thiol.

Subgroup 7: Species of first functional group (e.g., see claim 19)

Applicant must elect, for the purposes of search, a single species of first functional group e.g., α -halo acid.

Subgroup 8: Species of small organic ligand candidates (e.g., see claim 20)

Applicant must elect, for the purposes of search, a single species of small organic ligand candidates. The election should result in a particularly defined core structure that is shared by all library members. In defining this core structure, all variable groups should be defined (i.e. all atoms and bonds shown) as much as possible. However, if no common core structure exists, a representative example of the library must be elected. Furthermore, the "functional groups" reactive with the SME must be indicated e.g., thiol (see claim 21).

Subgroup 9: Species of conditions for step (v) (e.g., see claims 22-23)

Applicant must elect, for the purposes of search, a single species of conditions e.g., dithiothreitol.

Subgroup 10: Species of identification (e.g., see claim 34)

Applicant must elect, for the purposes of search, a single species of identification e.g., mass spectrometry.

Subgroup 11: Species of detectable tag (e.g., see claim 35)

Applicant must elect for purposes of search a single species of detectable tag. Furthermore, applicant must show **all** atoms and bonds that are necessary to define said

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detectable tag. Applicant should NOT use general notations like R^1 , R^2 , etc. when defining the structure because these labels represent more than one chemical group and thus more than one compound would be erroneously elected.

Subgroup 12: Species of covalently linked ligands (e.g., see claim 39)

Applicant must elect for purposes of search a *single species* of covalently linked ligands. Furthermore, applicant must show *all* atoms and bonds that are necessary to define said covalently linked ligands. Applicant should NOT use general notations like R^1 , R^2 , etc. when defining the structure because these labels represent more than one chemical group and thus more than one compound would be erroneously elected.

8. If applicant elects the inventions of Groups II-III, applicant is required to elect from the following patentably distinct species. Claim 44 and 48 are generic for groups II and III, respectively.

Subgroup 1: Species of molecule (e.g., see claims 44 and 48)

Applicant must elect, for the purposes of search, a *single species* of molecule wherein a *specific structure* is set forth, which clearly shows all of the atoms and bonds that are necessary to define said molecule. Applicant should *not* use notations like X or R when identifying the elected structure because these letters represent groups with variable members and, as a result, more than one species would be erroneously elected.

9. **Please Note:** Applicants must disclose which claims read on the elected species (see paragraphs 13 and 14 below).

10. The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have

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different issues regarding patentability and represent patentably distinct subject matter.

Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

11. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

12. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

13. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

14. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, *applicant must indicate which are readable upon the elected species*. MPEP § 809.02(a).

15. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.43). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

16. Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

17. Applicant is also reminded that a 1 – month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an “action on the merits” for purposes of the second action final program, see MPEP 809.02(a).

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (703) 308-2423. The examiner can normally be reached Monday through Friday from 8:30 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-2439.

Jon D. Epperson, Ph.D.
September 7, 2003

BENNETT CELSA
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Bennett Celsa', written over the printed name and title.